REMARKS

Claims 1, 2, 4-7, 9-15, 17-30, and 32-34 are pending. Claim 7 has been amended as will be discussed below. Support for the amendment to the claim can be found throughout the specification and claims as originally filed and there is no new matter added as a consequence of the amendments.

This paper is submitted in response to the Office Communication dated May 14, 2004 and supplements the Amendment filed February 26, 2004. The arguments presented in the Amendment filed February 26, 2004 are incorporated herein. In the Office Communication dated May 14, 2004, the Examiner indicated that the Amendment filed February 26, 2004 was not fully responsive for not addressing the 35 U.S.C. § 112, first paragraph rejection for lack of enablement.

In a telephone conversation with Dana Lau, the Examiner has indicated that the Amendment filed February 26, 2004 was a bona fide response and that a response addressing the enablement rejection may be filed. The Examiner also indicated that the response to the Office Communication is due one month from the mail date of the Office Communication and that extensions of time may be obtained by filing an extension fee under 37 C.F.R. § 1.136(a).

The Rejections under 35 U.S.C. § 112, ¶1 Should Be Withdrawn

Claims 1, 2, 4-6, and 42 have been rejected under 35 U.S.C. § 112, first paragraph, because the Examiner alleges that the specification, while being enabling for an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide, wherein the

oligodeoxyribonucleotide is SEQ ID NO:1 and further comprising an adenoviral vector encoding CTLA4Ig, does not reasonably provide enablement for an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide having one or more NFκB binding sites, further comprising a viral vector. The Examiner alleges that the description does not provide particular guidance or direction for an isolated tolerogenic dendritic cell comprising any oligodeoxyribonucleotide having one or more NFκB binding sites, further comprising any viral vector and concludes that one of ordinary skill in the art at the time of the invention would have required undue experimentation at the time of the invention to make and use the invention commensurate with the full scope of the claims. The Examiner alleges that the quantity of experimentation required to practice the invention over the claimed scope would include the de novo determination of developing an isolated tolerogenic dendritic cell comprising any oligodeoxyribonucleotide having one or more NFκB binding sites, further comprising any viral vector and would require one of skill in the art to engage in trial and error experimentation.

Claims 7, 9-14, 44, 46, 47 and 48 have been rejected under 35 U.S.C. § 112, first paragraph, because the Examiner alleges that the specification, while being enabling for a method of producing an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide, wherein the oligodeoxyribonucleotide is SEQ ID NO:1, further comprising an adenoviral vector encoding CTLA4Ig, and further comprising incubating said isolated tolerogenic dendritic cell in the presence of GM-CSF, does not reasonably provide enablement for a method of producing an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide having one or more NFκB binding sites, further comprising a viral

vector, and further comprising incubating said isolated tolerogenic dendritic cell in the presence of one or more cytokines or TGF-β. The Examiner alleges that the quantity of experimentation required to practice the invention over the claimed scope would include the de novo determination of developing a method of producing an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide having one or more NFκB binding sites, further comprising a viral vector, and further comprising incubating said isolated tolerogenic dendritic cell in the presence of one or more cytokines or TGF-β and would require one of skill in the art to engage in trial and error experimentation.

Claims 15, 17-29, 50, and 52-57 have been rejected under 35 U.S.C. § 112, first paragraph, because the Examiner alleges that the specification, while being enabling for a method of enhancing tolerogenicity in a mammalian transplant host, comprising the intravenous administration of an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide, wherein the oligodeoxyribonucleotide is SEQ ID NO:1, further comprising an adenoviral vector encoding CTLA4Ig, and further comprising incubating said isolated tolerogenic dendritic cell in the presence of GM-CSF, does not reasonably provide enablement for a method of enhancing tolerogenicity in a mammalian host with an inflammatory related disease or arthritis, comprising any route of administration of an isolated isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide having one or more NFκB binding sites, further comprising a viral vector, and further comprising incubating said isolated tolerogenic dendritic cell in the presence of one or more cytokines, TGF-β, FK 506, or cyclosporine A. The Examiner alleges that the quantity of experimentation required to practice the invention over the claimed scope would

include the de novo determination of a method of enhancing tolerogenicity in a mammalian host with an inflammatory related disease or arthritis, comprising any route of administration of an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide having one or more NFκB binding sites, further comprising a viral vector, and further comprising incubating said isolated tolerogenic dendritic cell in the presence of one or more cytokines, TGF-β, FK 506, or cyclosporine A and would require one of skill in the art to engage in trial and error experimentation.

Claims 30, 32-34, 64, and 65 have been rejected under 35 U.S.C. § 112, first paragraph, because the Examiner alleges that the specification, while being for a kit for enhancing tolerogenicity in a mammalian transplant host comprising an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide, wherein the oligodeoxyribonucleotide is SEQ ID NO:1, further comprising an adenoviral vector encoding CTLA4Ig, does not reasonably provide enablement for a kit for enhancing tolerogenicity in a mammalian host, comprising an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide having one or more NFκB binding sites, further comprising a viral vector. The Examiner alleges that the quantity of experimentation required to practice the invention over the claimed scope would include the de novo determination of developing a kit for enhancing tolerogenicity in a mammalian host, comprising an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide having one or more NFκB binding sites, further comprising a viral vector, and would require one of skill in the art to engage in trial and error experimentation.

Applicants respectfully traverse the rejections. The claimed invention must be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F2d. at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Applicants submit that the specification provides support and guidance for one of skill in the art to make and use the full scope of the claimed invention without undue experimentation. The claim amendments and rejections are discussed below.

With regard to claims 1, 2, and 4-6, Applicants submit that the specification clearly enables one of skill in the art make and use an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide having one or more NF-κB binding sites, wherein the NF-κB binding sites inhibit NF-κB transcriptional activity, wherein the oligodeoxyribonucleotide has the sequence set forth in SEQ ID NO:1. Furthermore, claim 1, as amended, corresponds substantively to cancelled claim 41, which the Examiner deemed allowable in the Office Action mailed August 26, 2003. Claim 42 has been cancelled, therefore the rejection of this claim is rendered moot.

With regard to claims 7 and 9-14, Applicants submit that the specification clearly enables a method of producing an isolated tolerogenic dendritic cell comprising propagating an immature isolated dendritic cell from a mammalian donor, incubating the immature isolated dendritic cell with an oligodeoxyribonucleotide having at least one NF-κB binding site under conditions wherein the immature isolated dendritic cell internalizes the oligodeoxyribonucleotide, wherein the NF-κB binding sites inhibit NF-κB transcriptional activity and culturing the isolated dendritic cell of to produce the isolated tolerogenic dendritic cell, wherein the

oligodeoxyribonucleotide has the sequence set forth in SEQ ID NO:1. Claim 7 has been amended herein to incorporate the subject matter of cancelled claim 8. Furthermore, the Examiner has indicated that the specification is enabling for a method of producing an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide, wherein the oligodeoxyribonucleotide is SEQ ID NO:1. Claims 44, 46, 47 and 48 have been cancelled, therefore the rejection of these claims are rendered moot.

With regard to claims 15 and 17-29, Applicants submit that the specification clearly enables a method for enhancing tolerogenicity in a mammalian host comprising propagating immature isolated dendritic cells from a mammalian donor, incubating the immature isolated dendritic cells with an oligodeoxyribonucleotide having at least one NF-κB binding site under conditions wherein the immature isolated dendritic cells internalize the oligodeoxyribonucleotide, wherein the NF-κB binding sites inhibit NF-κB transcriptional activity, culturing the isolated dendritic cells of (b) to produce isolated tolerogenic dendritic cells, and administering said isolated tolerogenic dendritic cells to said host, wherein the oligodeoxyribonucleotide has a sequence set forth in SEQ ID NO:1. Furthermore, the Examiner has indicated that the specification is enabling for a method of enhancing tolerogenicity in a mammalian transplant host, comprising the intravenous administration of an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide, wherein the oligodeoxyribonucleotide is SEQ ID NO:1. Claims 50 and 52-57 have been cancelled, therefore the rejection of these claims are rendered moot.

With regard to claims 30 and 32-34, Applicants submit that the specification clearly

enables a kit for enhancing tolerogenicity in a mammalian host comprising tolerogenic dendritic cells which comprise an oligodeoxyribonucleotide having at least one NF-κB binding site, wherein the NF-κB binding sites inhibit NF-κB transcriptional activity, wherein the oligodeoxyribonucleotide has a sequence set forth in SEQ ID NO:1. Furthermore, claim 30, as amended, corresponds substantively to cancelled claim 63, which the Examiner deemed allowable in the Office Action mailed August 26, 2003. The Examiner has also indicated that the specification is enabling for a kit for enhancing tolerogenicity in a mammalian transplant host comprising an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide, wherein the oligodeoxyribonucleotide is SEQ ID NO:1. Claims 64 and 65 have been cancelled, therefore the rejection of these claims are rendered moot.

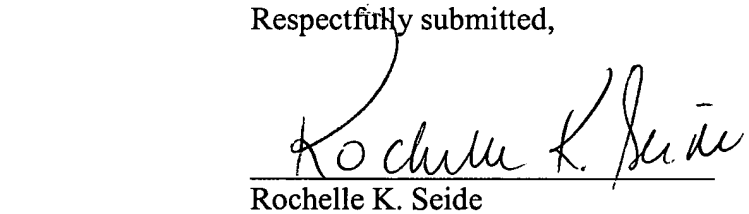
For the foregoing reasons, Applicants submit the claimed invention is enabled so that any person skilled in the art can make and use the invention without undue experimentation. Applicants respectfully request the withdrawal of the rejection of claims 1, 2, 4-7, 9-15, 17-30 and 32-34 under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request withdrawal of the outstanding rejections and allowance of the pending claims.

Applicants do not believe that any fee is required in connection with the submission of this document. However, should any fee be required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this sheet is enclosed.

Respectfully submitted,



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